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Progress report: Eastern Cooperative Oncology Group (ECOG) E5597, an intergroup phase iii randomized double blind chemoprevention trial of selenium supplementation in resected stage i non small cell lung cancer

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Selenium in the form of selenized yeast was reported by Clark et al. to have possible lung cancer chemopreventive benefits based on a secondary observation emanating from a large skin cancer prevention trial. (JAMA 1996; 276: 1957-1963). Since that time, epidemiologic, in vitro, and therapeutic research studies have continued to support the hypothesis that non-toxic selenium supplementation may decrease the risk of aerodigestive cancer in persons at high risk, e.g., those with resected bronchogenic cancer. Since October 2000, the Eastern Cooperative Oncology Group (ECOG) with support from the National Cancer Institute Division of Cancer Prevention (NCI-DCP) has been conducting an intergroup double blind placebo controlled trial using 200 micrograms of Selenium in a 2:1 randomization versus placebo. Eligibility requirements include completely resected Stage I (T1 or T2, N0) non-small cell cancer of the lung with a minimum of 1 negative mediastinal lymph node. Pts must have normal level of selenium / vitamin intake, satisfactory liver function, a negative chest x-ray and no other evidence of recurrence. Enrollment is allowed from 6 to 36 months post thoracotomy. A four wk run-in period is required during which pts must take at least 75% of the study drug to document compliance. As of March 7, 2007, 1268 pts have enrolled out of a projected total study size of 1960 participants. Treatment is for 48 months. Study endpoints include cancer recurrence, incidence of second primary lung tumors (SPTs), and/or toxicity. Treatment appears to be extremely well tolerated in this study. As of December 2006, a total of 363 patients on randomized step have reported treatment-related toxicities. Only six of them reported toxicities of grade 3 or higher as a worst toxicity. 133 grade 3, 4, or 5 severe adverse events have been reported with no difference between study drug and placebo. A total of six cooperative groups are participating in this ambitious project. Selenium appears to be very well tolerated in this setting. Accrual is projected to continue until 1960 pts have enrolled or until 90 SPTs have occurred.

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Usefulness of autofluorescence bronchoscopy for detecting bronchial premalignant lesions

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Background: Autofluorescence bronchoscopy (AFB), when used as an adjunct to conventional white light bronchoscopy (WLB) improves the bronchoscopist's ability to localized small intraepithelial lesions. Current study was undertaken to evaluate prevalence of preinvasive intraepithelial lesions (dysplasia II-III & CIS) and efficacy of additional AFB system to WLB in comparison with WLB alone.

Methods: In patients with suspicion of lung cancer or follow-up ones with known lung cancer, WLB (Pentax; BP 3500, Japan) and AFB (Richard Wolf, Germany) were done and all subjects with endoscopic abnormalities underwent biopsies from January 2005 to December 2005.

Results: 169 patients (134 suspected to have lung cancer radiologically, 18 with known lung cancer, and 17 with initial abnormal WLB visual findings) were enrolled. Overall preinvasive intraepithelial lesions were detected in 6.5% (n=11). Biopsy based sensitivity of WLB+AFB and WLB alone for detecting preinvasive intraepithelial lesions was 77.8% compared with 22.2% (relative ratio 3.5, 95% CI 0.93-13.24). Corresponding specificity was 56.9% compared with 89.2% (relative ratio 0.64, 95% CI 0.54-0.75). The positive predicitve value was 6% and 3%, and the negative predictive value was 94% and 87%, respectively, for WLB+AFB and WLB alone.

Conclusions: WLB+AFB was superior to WLB alone in detecting preinvasive intraepithelial lesions, but general use of AFB as a screening tool seems to be limited in suspected or known lung cancer group because of low prevalence. It is necessary of further study for precise indication for AFB among the lung cancer risk groups.

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Aberrant DNA methylation profiles of non-small cell lung cancers in a korean population

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We performed this study to investigate the aberrant methylation profile of the cancer-related genes in Korean non-small cell lung cancer (NSCLC) that previously exhibited high frequencies of methylation in Western populations. The aberrant promoter methylation of eight genes (GSTP1, p16, FHIT, APC, RASSF1A, hMLH1, hMSH2, AGT) was determined by MSP in 99 surgically resected NSCLCs and their corresponding nonmalignant lung tissues. Methylation in the tumor samples was detected at 15% for GSTP1, 22% for p16, 34% for FHIT1, 48% for APC, 40% for RASSF1A, 18% for hMLH1, 8% for hMSH2 and 21% for AGT, whereas it occurred at lower frequencies in the corresponding nonmalignant lung tissues, particularly in the p16 (1%) and RASSF1A (1%) genes. These results suggest that the methylation profiles of NSCLCs in a Korean population are similar to those in Western populations.